

IN THE CLAIMS

Please add new claims 93-95, as indicated in the following list of pending claims.

PENDING CLAIMS

1. (Previously Presented) A medical device for localization of tissue at a target site comprising:

an elongated shaft which has a distal shaft portion with a distal tip and a proximal shaft portion and which is configured for placement of the distal shaft portion into a patient's body at a desired target site;

a tissue penetrating element disposed on said distal tip; and

at least one fixation element which has a free end configured to secure the distal shaft portion within tissue at the target site, which has another end secured to the distal shaft portion at a location proximal of said distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site.

2-48. (Canceled)

49. (Previously Presented) The medical device of claim 1, wherein said tissue penetrating element is an electrosurgical cutting element.

50-51. (Canceled)

52. (Previously Presented) The medical device of claim 1, wherein the free end of the fixation element is configured for penetrating tissue.

53. (Previously Presented) The medical device of claim 1, wherein said fixation element is radially extendable and retractable from a side of the distal shaft portion.

54. (Previously Presented) The medical device of claim 53, wherein a plurality of fixation which are radially extendable and retractable from a side of the distal shaft portion.

55. (Previously Presented) A method of performing a medical procedure within a patient's body, comprising:

a) providing a medical device comprising a shaft having a distal portion with a tip, a proximal portion, a fixation element on the distal portion which has a free end and another end secured to the distal shaft portion at a location proximal to the distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site and a tissue penetrating element disposed on said distal tip,

b) placing the distal shaft portion into the patient's body, so that the distal end is disposed within the target site; and

c) extending into tissue at the target site the free end of the fixation element so that the distal portion of the shaft becomes secured within the target site.

56. (Previously Presented) The method of claim 55, wherein said fixation element is radially extendable and retractable from a side of the distal shaft portion.

57. (Previously Presented) The method of claim 55, wherein the medical device has a plurality of radially extendable and retractable fixation elements.

58. (Previously Presented) A method of performing a medical procedure, comprising:

- a) providing a medical device comprising a shaft having a distal shaft portion with a distal tip, a tissue penetrating element disposed on the distal tip, a proximal portion, a fixation element which has a free end and another end secured to the distal shaft portion at a location spaced proximal to the distal tip,
- b) advancing the tissue penetrating element on the distal tip through tissue of a patient's body;
- c) placing the distal shaft portion within a patient's body, so that the distal shaft portion is disposed adjacent target tissue; and
- d) radially extending into the target tissue the free end of the fixation element so that the distal portion of the shaft becomes secured adjacent the target tissue.

59. (Previously Presented) The method of claim 58, wherein said fixation element is radially extendable and retractable from a side of the distal shaft portion.

60. (Previously Presented) The method of claim 58, wherein the medical device has a plurality of radially extendable and retractable fixation elements.

61. (Previously Presented) The method of claim 58, wherein the tissue penetrating element is an electrosurgical cutting element.

62-64. (Cancelled)

65. (Previously Presented) A method for acquiring a tissue specimen from target site, comprising:

a) providing a tissue acquisition device having a shaft with a distal end with a distal tip, a proximal end, a distal cutting element disposed on said distal tip, a distal shaft portion, a fixation element which has a free end configured to engage target tissue, which has another end secured to the distal shaft portion at a location spaced proximally from the distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site,

b) placing the distal end of the shaft within a patient's body, so that the distal tip is disposed distally adjacent the target site;

c) securing the distal end of the shaft within the target site by extending into tissue at the target site the free end of the fixation element; and

d) acquiring a tissue specimen the target site.

66. (Cancelled)

67. (Previously Presented) The method of claim 65, wherein the tissue acquisition device has a plurality of fixation elements which extend from a location on the distal shaft portion spaced proximal to the distal end into tissue at the target site.

68. (Previously Presented) A medical device for localization of tissue at a target site within a patient's body, comprising:

a shaft having a distal shaft portion with a distal tip, and being configured for placement within the patient's body at target site;

a radially expandable side-cutting element which has an expanded configuration for cutting a tissue sample from target tissue and which is disposed on said shaft proximal of said distal tip; and

a fixation element which has a free end, which has another end secured to the distal shaft portion proximal of said distal tip and which is configured for securing the distal shaft portion of said medical device within tissue at said desired target site.

69. (Allowed) The medical device of claim 68, wherein said radially expandable side-cutting element is an electrosurgical cutting element.

70. (Previously Presented) The medical device of claim 68, wherein the free end of said fixation element is configured for penetrating tissue at the target site.

71. (Previously Presented) The medical device of claim 68, wherein said fixation element which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site.

72. (Previously Presented) The medical device of claim 71, wherein a plurality of radially extendable and retractable fixation elements are provided.

73. (Previously Presented) A method of performing a medical procedure at a target site within a patient's body, comprising:

a) providing a medical device comprising a shaft having a distal shaft portion with a distal tip, a fixation element which has a free end and another end secured to the distal shaft portion proximal to the distal tip, and a radially expandable side-cutting

element configured for cutting a tissue sample and disposed on said distal shaft portion proximal of said distal tip;

- b) advancing the distal shaft portion within a patient's body, so that the distal shaft portion is disposed within the target site; and
- c) extending into the target tissue the free end of the fixation element so that the distal shaft portion becomes secured within the target tissue.

74. (Previously Presented) The method of claim 73, wherein said fixation element has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site.

75. (Previously Presented) The method of claim 73, wherein said medical device comprises a plurality of radially extendable and retractable fixation elements.

76. (Previously Presented) A method for acquiring a specimen of tissue from a target site, comprising:

- a) providing a tissue acquisition device comprising a shaft having a distal end with a distal tip, a fixation element which has a free end and which is spaced proximal to the distal tip, and a radially expandable side-cutting element configured for cutting a tissue specimen and disposed on said shaft proximal of said distal tip;
- b) advancing the distal end of the shaft within a patient's body, so that the distal end is disposed within tissue at the target site;
- c) securing the distal end of the shaft within the tissue at the target site by extending into the tissue the free end of the fixation element; and
- d) cutting tissue with said radially expandable side-cutting element effective to separate one or more tissue specimens from the target site.

77. (Cancelled)

78. (Previously Presented) The method of claim 77, wherein the distal shaft portion is secured within tissue at the target site by extending a plurality of radially extendable and retractable fixation elements from a side of the distal shaft portion spaced proximal to the distal end.

79. (Allowed) A medical device for localization of target tissue comprising:
a shaft having a distal end with a distal tip, and being configured for placement of said distal end into a patient's body at a desired location;
a distal cutting element disposed on said distal tip;
a radially expandable side-cutting element configured for cutting a tissue sample from target tissue and disposed on said shaft proximal of said distal tip; and
a fixation element which has a free end, which is disposed on said distal end proximal of said distal tip and which is configured for securing the distal end of said medical device within target tissue at said desired location.

80. (Allowed) The medical device of claim 79, wherein said radially expandable side-cutting element is an electrosurgical cutting element.

81. (Allowed) The medical device of claim 79, wherein said distal cutting element is an electrosurgical cutting element.

82. (Allowed) The medical device of claim 79, wherein said fixation element is configured for penetrating tissue.

83. (Allowed) The medical device of claim 79, wherein said fixation element comprises at least one radially extendable and retractable member.

84. (Allowed) The medical device of claim 83, wherein said fixation element comprises a plurality of radially extendable and retractable members which are radially extendable and retractable from a side of the distal end of the shaft, said members having free ends and being configured for securing the distal end of the shaft adjacent target tissue.

85. (Allowed) A method of performing a medical procedure, comprising

a) providing a medical device comprising a shaft having a distal end with a distal tip, a distal cutting element on the distal tip, a radially expandable side-cutting element configured for cutting a tissue sample and disposed on said shaft proximal of said distal tip, and a fixation element which has a free end, which is spaced proximal to the distal tip and which is configured for engaging tissue,

b) advancing the medical device within a patient's body while cutting through tissue with said distal cutting element until the distal end of the shaft is disposed within target tissue; and

c) extending into the target tissue the free end of the fixation element so that the distal end of the shaft becomes secured within the target tissue.

86. (Allowed) The method of claim 85, wherein said fixation element comprises at least one radially extendable and retractable member.

87. (Allowed) The method of claim 86, wherein said fixation element comprises a plurality of radially extendable and retractable members.

88. (Allowed) The method of claim 85, wherein said distal cutting element is an electrosurgical cutting element.

89. (Allowed) The method of claim 85, wherein said cutting step comprises cutting target tissue.

90. (Allowed) The method of claim 85, wherein said cutting step comprises cutting through target tissue.

91. (Allowed) The method of claim 90, wherein said placing step comprises placing the distal end of the shaft in a patient's body so that the distal tip of the distal end is disposed adjacent and distal to target tissue.

92. (Previously Presented) A medical device for localization of target tissue comprising:

- a. an elongated shaft which has a distal portion with a distal tip and a proximal portion and which is configured for placement of the distal portion into a patient's body tissue at a desired location;
- b. a tissue penetrating cutting element disposed on the distal tip; and
- c. a plurality of fixation elements which have free ends configured to engage target tissue, at least one of the free ends being oriented in a proximal direction and at least one of the free ends being oriented in a distal direction and which are secured to the distal portion at locations proximal of the distal tip..

93. (New) A tissue-separating biopsy assembly comprising:

- a. a rotatable shaft having a distal shaft portion;
- b. a tissue separator element extending along the shaft and having a distal separator part at the distal shaft portion movable between a retracted state, towards the distal shaft portion, and an outwardly extending, operational state, away from the distal shaft portion; and
- c. a localization device at the distal shaft portion movable from a first, radially-contracted state to a second, radially-expanded state to capture a tissue section separated from surrounding tissue by the tissue separator device.

94. (New) A method for separating and capturing a tissue section from surrounding tissue of a patient, comprising:

- a. directing a localization device along a tissue tract to a position distal to a target site;
- b. changing the localization device from a first, radially-contracted state to a second, radially-expanded state;
- c. separating a tissue section at the target site from surrounding tissue; and
- d. encapsulating the separated tissue section to effectively capture the separated tissue section.

95. (New) The method of claim 93 wherein the localization and the captured separated tissue section.